

# Considerations for Monkeypox Vaccination

## What You Need to Know

- Two vaccines licensed by the U.S. Food and Drug Administration (FDA) are available for preventing monkeypox infection – JYNNEOS (also known as Imvamune or Imvanex) and ACAM2000.
- In the United States, there is currently a limited supply of JYNNEOS, although more is expected in coming weeks and months.
- There is an ample supply of ACAM2000. However, this vaccine should not be used in people who have some health conditions, including a weakened immune system, skin conditions like atopic dermatitis/eczema, or pregnancy.
- No data are available yet on the effectiveness of these vaccines in the current outbreak.
- People are considered fully vaccinated about 2 weeks after their second shot of JYNNEOS and 4 weeks after receiving ACAM2000. However, people who get vaccinated should continue to take steps to [protect themselves from infection](#) by avoiding close, skin-to-skin contact, including intimate contact, with someone who has monkeypox.
- To better understand the protective benefits of these vaccines in the current outbreak, CDC will collect data on any side effects and whether the way the person was infected makes any difference in how well the vaccine protects them.

## Vaccine Strategies to Prevent Monkeypox

When properly administered before or after a recent exposure, vaccines can be effective tools at protecting people against monkeypox illness. The following vaccination strategies are being used in the United States:

- **Monkeypox Vaccine Post-Exposure Prophylaxis (PEP):** For the current outbreak, this approach can be considered as “standard PEP” for monkeypox. People can be vaccinated following exposure to monkeypox to help prevent illness from monkeypox virus. It is important that states and other jurisdictions identify contacts of confirmed or probable monkeypox cases to offer vaccine for PEP and to monitor for any early signs of illness. CDC recommends that the vaccine be given within 4 days from the date of exposure for the best chance to prevent onset of the disease. If given between 4 and 14 days after the date of exposure, vaccination may reduce the symptoms of disease, but may not prevent the disease. However, when coupled with self-isolation and other prevention measures when symptoms first occur, PEP is important for controlling outbreaks and preventing further transmission of monkeypox.
- **Outbreak Response Monkeypox Vaccine Post-Exposure Prophylaxis (PEP)++:** For the current outbreak, this expanded approach can be considered as “individual-directed PEP” for monkeypox; public health officials refer to it as “expanded PEP” or “PEP plus-plus” or “PEP++”. People with certain risk factors are more likely to have been recently exposed to monkeypox. The PEP++ approach aims to reach these people for post-exposure prophylaxis, even if they have not had documented exposure to someone with confirmed monkeypox. When coupled with self-isolation and other prevention measures when symptoms first occur, PEP++ may help slow the spread of the disease in areas with large numbers of monkeypox cases—which would suggest a higher level of monkeypox virus transmission.
- **Monkeypox Vaccine Pre-Exposure Prophylaxis (PrEP):** This approach refers to administering vaccine to someone at high risk for monkeypox (for example, laboratory workers who handle specimens that might contain monkeypox virus). At this time, most clinicians in the United States and laboratorians not performing the orthopoxvirus generic test to diagnose orthopoxviruses, including monkeypox virus, are not advised to receive monkeypox vaccine PrEP.

## Vaccine Information (JYNNEOS and ACAM2000)

JYNNEOS vaccine is being allocated to jurisdictions for use for the following individuals:

- Known contacts who are identified by public health via case investigation, contact tracing, and risk exposure assessments

- Presumed contacts who may meet the following criteria:
  - Know that a sexual partner in the past 14 days was diagnosed with monkeypox
  - Had multiple sexual partners in the past 14 days in a jurisdiction with known monkeypox

JYNNEOS doses should be prioritized for those people who are at risk for severe adverse events with ACAM2000 or severe disease from monkeypox (such as people with HIV or other immunocompromising conditions).

JYNNEOS*	ACAM2000
<ul style="list-style-type: none"> <li>• JYNNEOS contains a live virus that does not replicate efficiently in human cells.</li> <li>• Administered as two subcutaneous injections four weeks apart.</li> <li>• The immune response takes 2 weeks after the second dose for maximal development.</li> <li>• Licensed by the FDA for use in the prevention of smallpox or monkeypox in people ages 18 years and older. Use in younger populations requires submission of a single patient Expanded Access Investigational New Drug (IND) application.</li> <li>• The effectiveness of JYNNEOS against monkeypox is supported by animal studies.</li> <li>• There are no data on the efficacy of JYNNEOS for PEP or PrEP from the current outbreak. Although this is also true for ACAM2000, there is evidence that the related Dryvax vaccine worked well during the smallpox eradication period. Public health officials have concern about the lack of efficacy data for JYNNEOS, especially because it requires two doses 28 days apart.</li> <li>• Adverse reactions include injection site reactions such as pain, swelling, and redness.</li> <li>• People with a severe allergy to any component of the vaccine (gentamicin, ciprofloxacin, egg protein) should not receive this vaccine.</li> <li>• Safe for administration to people with HIV and atopic dermatitis.</li> <li>• While there are no data in people who are pregnant or breastfeeding, animal data do not show evidence of reproductive harm; pregnancy and breastfeeding are not contraindications.</li> </ul>	<ul style="list-style-type: none"> <li>• ACAM2000 is a live <i>Vaccinia virus</i> vaccine that is replication competent.</li> <li>• Administered as one percutaneous dose via multiple puncture technique with a bifurcated needle.</li> <li>• The immune response takes 4 weeks for maximum development.</li> <li>• Following a successful inoculation, a lesion (known as a “take”) will develop at the site of the vaccination; the lesion may take up to 6 weeks or more to heal.</li> <li>• Licensed by the FDA for use against smallpox; allowed for use against monkeypox under an Expanded Access IND, which requires informed consent along with submission of additional forms.</li> <li>• The effectiveness of ACAM2000 is supported by human clinical trials and animal studies.</li> <li>• There are no data on the efficacy of ACAM2000 for PEP or PrEP from the current outbreak.</li> <li>• Adverse reactions include injection site pain, swelling, and redness; fever; rash; lymph node swelling; and complications from inadvertent inoculation.</li> <li>• People with severe allergy to any component of the vaccine should not receive it. In addition, people with severely weakened immune systems should not receive this vaccine.</li> <li>• ACAM2000 should not be given to people with the following conditions:           <ul style="list-style-type: none"> <li>◦ Cardiac disease</li> <li>◦ Eye disease treated with topical steroids</li> </ul> </li> </ul>

JYNNEOS*	ACAM2000
	<ul style="list-style-type: none"> <li>◦ Congenital or acquired immune deficiency disorders, including those taking immunosuppressive medications and people living with HIV (regardless of immune status)</li> <li>◦ Atopic dermatitis/eczema and persons with a history of atopic dermatitis/eczema or other acute or exfoliative skin conditions</li> <li>◦ Infants less than 12 months of age</li> <li>◦ Pregnancy</li> </ul>

\*On November 3, 2021, the Advisory Committee on Immunization Practices (ACIP) voted to recommend JYNNEOS pre-exposure prophylaxis as an alternative to ACAM2000 for certain persons at risk for exposure to orthopoxviruses.

## Planning Considerations for Health Departments and Providers

- **Access to Vaccine**

- Both vaccines are available from the Strategic National Stockpile (SNS) and can be requested in consultation with CDC.
- Either JYNNEOS or ACAM2000 can be used for PEP, PEP++, or PrEP, following risk-benefit discussions and a review of any conditions that could increase risk for serious adverse events.

- **Equity**

- When developing vaccine plans, consider the following approaches to ensure equitable distribution:
  - Engage diverse partners already working with special populations
  - Use non-stigmatizing language
  - Reiterate privacy of information and how data will be used
  - Bring vaccines to where people are through pop-up events and mobile outreach
  - Engage people with lived experience in planning and through peer education models

- **Special Considerations for JYNNEOS**

- Two doses of JYNNEOS are required, as this is the only FDA-approved dosing regimen.
- JYNNEOS has been evaluated in clinical studies involving people with HIV infection and atopic dermatitis and shown to be safe and effective in eliciting an immune response in these populations.
- People who receive JYNNEOS are considered to reach maximum immunity 14 days after their second dose (~ 6 weeks from first dose). They should continue to take precautions against monkeypox during this time.
- We do not know if JYNNEOS will fully protect against monkeypox virus infection in this outbreak. Individuals wanting to minimize their risk of infection should take additional preventive measures and self-isolate as soon as they develop monkeypox symptoms, such as a rash. Infections despite vaccination may occur, and there is currently no data on effectiveness of JYNNEOS from the current outbreak.

- **Special Considerations for ACAM2000**

- Adverse events following ACAM2000, including myopericarditis or *Vaccinia virus* transmission to household contacts, can be serious. ACAM2000 will be made available for individuals who decide in consultation with their healthcare provider that the potential benefits of vaccination outweighs any potential risks from ACAM2000 adverse events.

- Recipients should be informed of the risks and benefits of ACAM2000 prior to vaccination. People who are eligible for and offered ACAM2000 should be tested for HIV to ensure they are HIV negative, counseled on potential side effects, and sign an informed consent. Recipients should be advised to keep the vaccination site covered and to avoid swimming, sharing of blankets and towels, and contact with people who might be at risk for serious adverse events, such as people with weakened immune systems, atopic dermatitis/eczema, children younger than 12 months, or people who are pregnant.
- Providers should advise the vaccine recipient on how to keep the vaccination site clean and covered until the lesion completely heals (up to 6 weeks or more). Providers should be properly trained on administration of ACAM2000 using a bifurcated needle and should follow up with the patient to assess the vaccination site for a vaccination “take.” (see [Smallpox Vaccination and Adverse Reactions](#)).
- Any provider can administer ACAM2000; training may be obtained online through [a CDC training video](#).
- People who receive ACAM2000 are considered to reach maximum immunity ~ 1 month after their dose. Until full immunity is reached, they need to take specific precautions to prevent spread of the vaccine virus to others, including through direct contact (including sexual contact).
- Since there is currently no data on the effectiveness of ACAM2000 from the current outbreak, people who get this vaccine should continue to take steps to [protect themselves from infection](#) even after vaccination takes full effect.
- **How previous smallpox vaccination may affect current recommendations for JYNNEOS**
  - Previous smallpox vaccination does provide protection, but it may not necessarily be lifelong. During the 2003 monkeypox outbreak and during the current outbreak, several people who were infected with monkeypox had previously been vaccinated against smallpox decades prior.
  - In response to an outbreak, vaccines and other medical measures would also be given to eligible people who were previously vaccinated against smallpox.
    - See current ACIP recommendations for revaccination guidance for those at occupational risk of exposure.

## Resources

- [Vaccination Information | Smallpox | CDC](#)

### JYNNEOS

- [Use of JYNNEOS \(Smallpox and Monkeypox Vaccine, Live, Nonreplicating\) for Preexposure Vaccination of Persons at Risk for Occupational Exposure to Orthopoxviruses: Recommendations of the Advisory Committee on Immunization Practices — United States, 2022 | MMWR \(cdc.gov\)](#)
- JYNNEOS Package Insert. Available from: <https://www.fda.gov/media/131078/download> .
- [Vaccine Information Statement: Smallpox/Monkeypox Vaccine \(JYNNEOS™\): What You Need to Know \(cdc.gov\)](#) 

### ACAM2000

- [Use of Vaccinia Virus Smallpox Vaccine in Laboratory and Health Care Personnel at Risk for Occupational Exposure to Orthopoxviruses — Recommendations of the Advisory Committee on Immunization Practices \(ACIP\), 2015 | MMWR \(cdc.gov\)](#)
- ACAM2000 Product Insert. Available from: <https://www.fda.gov/media/75792/download> .
- [Medication Guide Smallpox Vaccine, Live ACAM2000 \(fda.gov\)](#) 
- [Administering ACAM2000 Smallpox Vaccine Videos | Smallpox | CDC](#)
- [Surveillance Guidelines for Smallpox Vaccine \(vaccinia\) Adverse Reactions \(cdc.gov\)](#)
- [Recommendations for Using Smallpox Vaccine in a Pre-Event Vaccination Program: Supplemental Recommendations of the Advisory Committee on Immunization Practices \(ACIP\) and the Healthcare Infection Control Practices Advisory Committee \(HICPAC\) \(cdc.gov\)](#)
- [Smallpox Vaccination and Adverse Reactions \(cdc.gov\)](#)
- [Smallpox \(ACAM2000\) | Health.mil](#) 